

Rejection of Claims 25-34 Under 35 U.S.C. Section 101

Claims 25-34 are rejected under 35 U.S.C. Section 101 as lacking a credible, substantial, specific or well-established utility. Applicants respectfully traverse this rejection.

In Applicants Preliminary Amendment ("Amendment") filed on October 10, 2001, an Exhibit A was filed which showed the homology between GERP and BS203. The Examiner did not find Applicants comparison between GERP and BS203 persuasive because the comparison between the sequences was not provided in the form of a declaration. The Examiner also raised a number of questions regarding Exhibit A.

Applicants enclose the declaration of Edward Granados under 37 C.F.R. Section 1.132 ("Declaration"). In the Declaration, Mr. Granados explains how the comparison between BS203 and GERP in Exhibit A was conducted.

In the office Action, the Examiner stated that the GERP sequence appeared to be 2646 nucleotides in length and that the relationship between the nucleotide sequences between BS203 shown in the above-identified application and that shown in Exhibit A was unclear. The nucleotide sequence of BS203 in the specification is 1332 base pairs in length. Exhibit A shows BS203 from base pairs 7 – 1399. When 7 is subtracted from 1399, the resulting length is 1332, which is what is disclosed in the specification. Applicants hope that this explanation is clear to the Examiner.

The Examiner also indicated that Exhibit A contained three additional lines that were not labeled. The three lines represent the three possible translations for the BS203 and GERP sequences. The analysis shows that the middle translation yields the most open reading frame of the three possibilities. The middle line also shows that all of the BS203 sequence can be attributed to an open reading frame.

As Applicants discussed in their Amendment in attached Exhibit B, GERP is expressed in a variety of tumors, including adenocarcinomas. As demonstrated in attached Exhibit C in the Amendment, adenocarcinomas comprise about 95% of breast malignancies.

Applicants submit that the information provided in the enclosed Declaration is sufficient to establish that BS203 is a RING finger protein. However, in the Office Action, the Examiner stated that even if Applicants were able to provide evidence to support this assertion, the specification as originally filed did not contemplate or characterize BS203 as a RING finger protein. Applicants submit that there is no requirement under the law that its specification characterize BS203 as being a specific type of protein. Instead, in their specification, Applicants describe how BS203 can be used as a diagnostic marker for the diagnosis of breast tissue disease or condition, particularly breast cancer. These statements are consistent with those functions described for other RING finger proteins, such as GERP, to which BS203 exhibits a high level of homology. Therefore, it is clear that BS203 exhibits utility as a diagnostic tool in detecting breast cancer. Thereupon, in light of the above arguments, Applicants submit that this rejection should be withdrawn.

Rejection of Claims 25-34 Under 35 U.S.C. Section 112, First Paragraph

Claims 25-34 are rejected under 35 U.S.C. Section 112, first paragraph. Specifically, the Examiner states that since the claimed invention is not supported by either a specific and substantial, or credible asserted utility or well-established utility that one skilled in the art would not know how to use the claimed invention. Applicants respectfully traverse this rejection.

In view of the arguments made in connection with the 35 U.S.C. Section 101 rejection, Applicants submit that this rejection has now been rendered moot and should be withdrawn.

Rejection of Claims 25 and 28-34 Under 35 U.S.C. Section 112, First Paragraph

Claims 25 and 28-34 were rejected under 35 U.S.C. Section 112, First Paragraph for a number of reasons. Specifically, the Examiner stated that these claims were broadly written to include nucleic acids in which sequences were “present flanking SEQ ID NO:1-13”. According to the Examiner, “[T]he broadest reasonable interpretation of the claims indicates that the claims are inclusive of BS203 genes and BS203 genomic sequences. However, the specification does not teach any full length BS203 genes or any BS203 genomic sequences.” Applicants vigorously disagree and respectfully traverse this rejection.

Claim 25 is directed to certain isolated and purified polynucleotide sequences selected from the group consisting of certain SEQ ID NOS. Claims 32 is directed to a recombinant expression system comprising an isolated and purified nucleic acid sequence selected from the group consisting of certain SEQ ID NOS. Claims 25 and 32 have been amended. Applicants submit that the specification as filed contains an adequate written description to support the claims as amended. Therefore, this rejection should be withdrawn.

Rejection of Claim 26 Under 35 U.S.C. Section 112, Second Paragraph

Claim 26 was rejected under 35 U.S.C. Section 112, Second Paragraph as being indefinite. More specifically, the Examiner stated that the claim was unclear in view of the recitation “degenerate coding sequences thereof.”

Claim 26 has been amended to remove the recitation “degenerate coding sequences thereof.” In view of this amendment, Applicants submit that this rejection should be withdrawn.

Applicants submit that the claims are in condition for allowance.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If any additional fees

are incurred as a result of the filing of this paper, authorization is given to charge deposit account No. 01-0025.



23492

ABBOTT LABORATORIES  
Telephone: (847) 935-7550  
Facsimile: (847) 938-2623

Gardner, Carton & Douglas  
Quaker Tower  
321 North Clark Street  
Chicago, IL 60610-4795  
Phone: (312) 644-3000  
Fax: (312) 644-3381

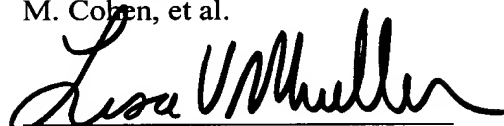
CH02/22173119.14

Respectfully submitted,  
M. Cohen, et al.

---

Mimi C. Goller  
Registration No. 39,046  
Attorney for Applicants

Respectfully submitted,  
M. Cohen, et al.



---

Lisa V. Mueller  
Registration No. 38,978  
Attorney for Applicants

**MARKED UP VERSION SHOWING CHANGES MADE:**

25. (Amended). An isolated and purified [specific] polynucleotide comprising a sequence selected from the group consisting of: SEQ ID NO:1, SEQUENCE ID NO:2, SEQUENCE ID NO:3, SEQUENCE ID NO:4, SEQUENCE ID NO:5, SEQUENCE ID NO:6, SEQUENCE ID NO:7, SEQUENCE ID NO:8, SEQUENCE ID NO:9, SEQUENCE ID NO:10, SEQUENCE ID NO:11, SEQUENCE ID NO:12, SEQUENCE ID NO:13, and SEQUENCE ID NO:14, full complements of SEQ ID NO:1, SEQUENCE ID NO:2, SEQUENCE ID NO:3, SEQUENCE ID NO:4, SEQUENCE ID NO:5, SEQUENCE ID NO:6, SEQUENCE ID NO:7, SEQUENCE ID NO:8, SEQUENCE ID NO:9, SEQUENCE ID NO:10, SEQUENCE ID NO:11, SEQUENCE ID NO:12, SEQUENCE ID NO:13, and SEQUENCE ID NO:14, and equivalent degenerate coding sequences thereof.

26. (Amended). The polynucleotide of claim 25, wherein the polynucleotide encodes a protein which comprises an amino acid sequence selected from the group consisting of SEQ ID NO:17[,] and full complements of SEQ ID NO:17 [and equivalent degenerate coding sequences thereof].

32. (Amended). A recombinant expression system comprising an isolated and purified nucleic acid sequence [that includes] having an open reading frame operably linked to a control sequence compatible with a desired host, wherein the nucleic acid sequence is selected from the group consisting of:  
SEQ ID NO:1, SEQUENCE ID NO:2, SEQUENCE ID NO:3, SEQUENCE ID NO:4, SEQUENCE ID NO:5, SEQUENCE ID NO:6, SEQUENCE ID NO:7, SEQUENCE ID NO:8, SEQUENCE ID NO:9, SEQUENCE ID NO:10, SEQUENCE ID NO:11, SEQUENCE ID NO:12, SEQUENCE ID NO:13, and SEQUENCE ID NO:14, full complements of SEQ ID NO:1, SEQUENCE ID NO:2, SEQUENCE ID NO:3, SEQUENCE ID NO:4, SEQUENCE ID NO:5, SEQUENCE ID NO:6, SEQUENCE ID NO:7, SEQUENCE ID NO:8, SEQUENCE ID NO:9, SEQUENCE ID NO:10, SEQUENCE ID NO:11, SEQUENCE ID NO:12, SEQUENCE ID NO:13, and SEQUENCE ID NO:14, and equivalent degenerate coding sequences thereof.